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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.*, GERALDINE GODECKE, Plaintiff, v. KINETIC CONCEPTS, INC., and KCI USA, INC., Defendants.	CASE NO. CV 08-06403 BRO (AGR) RELATOR GERALDINE GODECKE'S FOURTH AMENDED COMPLAINT *REDACTED*

I.
INTRODUCTION

1. This is an action to recover damages and civil penalties for the United States of America arising from false claims made by Kinetic Concepts, Inc., and KCI USA, Inc. (collectively KCI) to the Medicare health program related to the improper submission to Medicare of claims for payment for Negative Wound Pressure Therapy (NPWT) using its Vacuum Assisted Closure device (VAC), in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., as amended.

2. The False Claims Act (hereinafter the Act or FCA), enacted in 1863 during the Civil War, was substantially amended by the False Claims Amendments Act of 1986. Congress enacted these amendments to enhance the Government's ability to recover losses sustained from fraud against the United States and to provide a private cause of action for the protection of employees who act in furtherance of the purposes of the Act. Congress acted after finding that fraud in federal programs and procurement is pervasive and that the Act, which Congress characterized as the primary tool for combating fraud in government contracting, needed modernization.

3. The Act provides that any person who knowingly presents or causes to be presented a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government, including attorneys' fees. The Act allows any person having information regarding a false or fraudulent claim

against the Government to bring a private cause of action for himself (the Relator), and on behalf of the government, and to share in any recovery.

4. The FCA holds liable any person or entity who or that knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A).

5. The FCA was further amended by the Fraud Enforcement Recovery Act ("FERA") passed by Congress and signed into law on May 20, 2009 to strengthen the tools available to combat fraud and to overturn judicial decisions that had weakened the False Claims Act. Pub. L. No. 111-21, 123 Stat. 1617 (2009).

6. Although most of the new provisions apply only to claims after the effective date of the statute, Congress determined that 31 U.S.C. § 3729(a)(1)(B), which revised the former section designated as 31 U.S.C. § 3729(a)(2) pertaining to liability for false statements, "…shall take effect as if enacted on June 7, 2008, and shall apply to all claims . . . that are pending on or after that date." § 4(f) of FERA, 123 Stat. at 1625 (see note following 31 U.S.C. § 3729).

7. For claims before June 7, 2008, 31 U.S.C. § 3729(a)(2) holds liable any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." *Id.*

8. For claims after June 7, 2008, 31 U.S.C. § 3729(a)(1)(B) holds liable any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Id.

9. Plaintiff/Relator, Geraldine Godecke, seeks to recover damages and civil penalties arising from Defendant's presentation of false claims to the United States Government specifically through the Medicare health program through the improper billing and receipt of payments for its V.A.C device.

10. Relator Godecke, has direct and independent knowledge of Defendants' conduct that violated the False Claims Act. In bringing this claim Godecke does not rely on any public disclosure of KCI's fraudulent conduct, if any such prior disclosure exists. Moreover, she is an original source of the fact alleged herein, and she brought these claims to the attention of the Government before filing this action.

II.
PARTIES

11. Relator Godecke is a resident of Dillon, Montana. On June 1, 2001, she became employed by Med Claim, Inc. (MedClaim), a specialized billing company owned by Deborah Smith (aka Deb Smith), which was under contract with KCI to submit claims for VAC therapy to Medicare and to provide evidentiary and other support for KCI appeals of claims denied by Medicare. In approximately 2003, KCI purchased MedClaim and Godecke then became an employee of KCI. Godecke's position, when working for both MedClaim and KCI, was based in Dillon, Montana.

Godecke continued working for KCI until October 1, 2007. During her employment, she gained direct and independent knowledge of the allegations contained in this Complaint. She was the Director of Medicare Cash and Collections from June 1, 2001 until October 1, 2007, first for MedClaim and then for KCI. Her duties included cash posting to the KCI accounting system, which necessarily involved working with the KCI information systems related to billing. In performing these duties, Godecke and her staff received and reviewed every communication regarding a claim payment made to KCI by Medicare and every communication regarding a claim that was denied payment by Medicare. These included every Explanation of Benefits (EOBs) provided from insuring entities, including Medicare. She was also responsible for the creation of a new department within MedClaim dealing specifically with the appeal process for KCI's VAC claims that had been denied in the Medicare billing and payment system. Her department grew from two employees in June 2001 to as many as 105 employees by October 1, 2007. Godecke was responsible for developing all systems and procedures regarding the appeal process used by MedClaim and later KCI. Within MedClaim/KCI, her department was informally known as the "back end" of the billing department. In performing their duties related to appeals, Godecke and her staff reviewed claims denied by Medicare, and evaluated whether KCI should appeal those denials. If the decision was to proceed with an appeal, Godecke and her staff provided information support for challenging those denials in administrative

hearings before Administrative Law Judges (ALJs). When performing the work of evaluating whether KCI should appeal a Medicare claim denial, she and her staff reviewed all documentation for the claim and all documentation for prior KCI claims regarding the same patient. Godecke also worked closely with the management-level employees in the "front end" billing department at MedClaim/KCI to identify why Medicare denied KCI's claims and to recommend changes to KCI's documentation and billing processes to decrease denials. Godecke and her staff also had duties related to Medicare audits. As will be explained below, that work was similar to the work they performed on appeals of Medicare claim denials. Godecke was not part of the Billing Department, which was under the direction of Deb Smith. Beginning early in 2004 and continuing through late 2005, Godecke also managed KCI Ship Pending Customer Service Representatives (CSRs). It was in this capacity that she learned KCI's implementation procedures regarding the Medicare requirement that KCI obtain a properly completed Detailed Written Order prior to delivery of a VAC and noticed that KCI intentionally violated this Medicare requirement.

12. Defendant KCI, Inc. (KCI) manufactures and markets the VAC. KCI is headquartered in San Antonio, Texas and does business throughout the United States and the world. KCI's total Medicare Part B revenue from 2001 through 2011 was $1.325 billion.

13. Defendant KCI-USA, Inc. is a Delaware corporation that is a subsidiary of KCI. It is headquartered in San Antonio, Texas, and operates the service centers through which the VAC is rented to patients in the United States. Hereafter, the defendants will be jointly referred to as KCI and/or "defendant."

III.
JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to §§ 3729 and 3730 of Title 31, United States Code.

15. This Court has personal jurisdiction over KCI because KCI regularly conducts business in California. KCI has eleven (11) service centers throughout California including Van Nuys and Orange, California.

16. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because KCI routinely transacts business in the Los Angeles, California area.

IV.
BACKGROUND ON NWPT and VACs

17. KCI began manufacturing and marketing Negative Pressure Wound Therapy (NPWT) using a Vacuum Assisted Closure device in approximately 1995. The device is based on patents held by Wake Forest University and licensed exclusively to KCI in 1993.

18. Nearly all of KCI's Medicare revenue from 2000 - 2011 came from the VAC with only a minuscule amount from KCI's therapeutic surfaces, another line of its products.

19. KCI has described the VAC on its website as follows:

> KCI has revolutionized advanced wound care with the development of Negative Pressure Wound Therapy (NPWT). Utilizing multiple mechanisms of action, VAC Therapy removes fluids and infectious materials, helps protect the wound environment, helps promote perfusion and a moist healing environment and helps draw together wound edges.
>
> VAC Therapy is the controlled application of sub-atmospheric pressure to a wound using a therapy unit to intermittently or continuously convey negative pressure to a specialized wound dressing to help promote wound healing.
>
> The wound dressing is a resilient, open-cell foam surface dressing . . . that assists tissue granulation and is sealed with an adhesive drape that contains the sub-atmospheric pressure at the wound site.
>
> Special T.R.A.C. Technology enhances patient safety by regulating pressure at the wound site.
>
> Additionally, the VAC Therapy System helps direct drainage to a specially designed canister that reduces the risk of exposure to exudate fluids and infectious materials. (KCI Website, http://www.kci1.com)

20. Pursuant to Medicare Part B, the NPWT pump or VAC is rented monthly while the supplies needed to support this treatment, including dressings and a canister, are purchased.

A. MEDICARE TREATMENT OF NEGATIVE PRESSURE WOUND THERAPY PUMPS

21. In 1965, Medicare was established under Title XVII, Health Insurance for the Aged and Disabled, of the Social Security Act. Medicare is a federal government health insurance program for people age 65 or older, people under 65 with certain disabilities and people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant). The Centers for Medicare and Medicaid Services (CMS) is the agency of the U.S. Department of Health and Human Services (HHS) that administers the Social Security Act. Title 42 of the United States Code, Chapter 7, Subchapter XVIII, Part E, Section 1395 et seq. governs the Medicare program.

22. No Medicare payment may be made for any expense incurred for items or services which ". . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

23. Congress did not define "reasonable and necessary" in the legislation that created Medicare. Instead, Congress vested final authority in the Secretary of HHS to determine which items and services are not reasonable and necessary. 42 U.S.C. § 1395ff(a).

24. Section 1833(e) of the Social Security Act precludes payment to any provider of services unless there has been furnished such information as may be necessary to determine the amounts due to the provider. 42 U.S.C. § 1395 (e).

25. Part B of the Medicare program helps cover doctors' services and outpatient care. Part A of the Medicare program covers inpatient care in hospitals, critical access hospitals and skilled nursing facilities (not custodial or long-term care).

26. When Medicare approved Negative Pressure Wound Therapy (NPWT), it was assigned to the Durable Medical Equipment - Prosthetics, Orthotics and Supplies (DMEPOS) Benefit Category. Within that category, KCI's VAC and related supplies are classified as Durable Medical Equipment (DME), which is defined as "equipment which: can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally, is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home." Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, § 110.1. See also 42 C.F.R. § 414.202. For each item of DME, the Medicare program has a National Coverage Determination (NCD) or a Local Coverage Determination (LCD) that identifies circumstances under which Medicare will deny payment for the item as not reasonable and necessary.

27. The Health Care Finance Administration (HCFA) added the NPWT pump and its supplies to its list of Medicare covered DME on October 1, 2000. In

October 2000, KCI's VAC was the first and only NPWT pump on the Medicare approved DME list. In August 2001, HCFA was renamed the Centers for Medicare and Medicaid Services (CMS).

28. When used in a home setting for patients with Medicare Part B coverage, KCI's VAC is billed pursuant to Medicare Part B rules and regulations.

29. At the inception of the Medicare program in 1965, the health insurance and medical communities raised concerns that the enactment of Medicare would result in a large and unwanted Federal presence in the provision of health care. To address these concerns, sections 1816(a) and 1842(a) of the Social Security Act provided that public agencies and or private organizations could participate in the administration of the Medicare program under agreements or contracts entered with the Government. These legislative provisions created Fiscal Intermediaries (FI) and Carriers - private companies - to administer the Medicare program on behalf of the federal government. The entities handling Part B of Medicare are the Carriers.

30. 42 U.S.C. § 1395kk-1 provides:

> (a) Authority -
>
> (1) Authority to enter into contracts - The Secretary [of HHS] may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

* * *

3) Medicare administrative contractor defined. - For purposes of this title and title XI-
(A) In general - The term "medicare administrative contractor" means an agency, organization, or other person with a contract under this section.

(B) Appropriate medicare administrative contractor. - With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

(4) Functions described. - **The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1869(f)(2)(B)), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:** (emphasis added)

(A) Determination of payment amounts. - Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

(B) Making payments. - Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

> (C) Beneficiary education and assistance. - Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns, or problems.
>
> (D) Provider consultative services. - Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.
>
> (E) Communication with providers. - Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.
>
> (F) Provider education and technical assistance. - Performing the functions relating to provider education, training, and technical assistance.
>
> (G) Additional functions. - Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1893, as are necessary to carry out the purposes of this title.

31. The organizations that administer claims involving Durable Medical Equipment (DME) are known as DME MACs. The DME MACs were previously named Durable Medical Equipment Regional Carriers (DMERCs). (Throughout this Complaint, DMERCs and DME MACs will be used interchangeably.) Despite the name change, the organizations performed the same functions. There are four separate Regional DME MACs that serve the United States. The DME MACs are designated as Regions A, B, C and D. Each Region is headed by a Medical Director and has

responsibility for several states. These contractors handle the Medicare claims for KCI's VAC throughout the United States and American territories.

B. MEDICARE REIMBURSEMENT RATES FOR VACs

32. VAC therapy is billed in one-month cycles, as is all rented Durable Medical Equipment. Medicare Part B pays a monthly rental price for VACs and buys the supplies required to operate the device (wound dressings and canisters to collect waste). Unit reimbursement rates for each have varied over time as shown in the following table:

VAC UNIT REIMBURSEMENT 2002 - 2011

Year	VAC	Dressings (A6550)	Canisters (A7000)
2002	1716.46	27.28	24.41
2003	1716.46	27.42	24.53
2004	1716.46	27.42	9.54
2005	1716.46	27.47	9.54
2006	1716.46	27.47	9.54
2007	1716.46	27.42	9.54
2008	1716.46	27.42	9.54
2009	1716.46	24.82	8.63
2010	1553.40	24.82	8.63
2011	1551.85	24.80	8.62

33. In addition to a single monthly rental of a VAC, Medicare reimbursement allows up to 15 dressings and 10 canisters each month without additional documentation requirements.

34. Beginning in the fourth month, reimbursement for a VAC is reduced by 25% while the reimbursement for dressings and canisters remains unchanged.

35. Using the table above and taking 2006 as a typical year, the total monthly cost of a KCI VAC is about $2,224 for a Medicare patient for the first three months. All subsequent months after the third month are reimbursed at $1,287 for the pump (75% of $1,716) plus the supply cost of $507 for a total reimbursement of about $1,794 beginning in month 4. Medicare pays 80% of this cost and the patient is liable for the remaining 20%.

V.
MEDICARE DOCUMENTATION AND BILLING REQUIREMENTS FOR KCI'S NPWT/VAC

A. MEDICARE'S "PAY AND CHASE" CLAIMS SYSTEM

42 U.S.C. § 1395kk-1(a)(4)(A) & (B) authorizes the Fiscal Intermediaries/Carriers (including the DME MACs) to determine the amount of payment and to make payments on behalf of the Government to Medicare claimants. The Medicare program, through its Fiscal Intermediaries/Carriers, has historically paid claims quickly without verifying the accuracy of the claims before payment because it is required to pay claims submitted

electronically within fourteen (14) days of receipt of the claim and claims submitted in paper form in twenty-six (26) days of receipt of the claim. (See, Medicare Claims Processing Manual, Chapter 1, General Billing Requirements, Section 80.2.1.2) This payment system has become known throughout Medicare and among providers as "pay and chase." Medicare accepts claims as submitted by providers as being a true representation that the claim either qualifies for reimbursement or does not qualify and automatically pays those claims represented as qualifying. Medicare then must seek reimbursement or recoupment if it later determines that the claim should not have been paid.

36. CMS dictates how claims shall be handled and has issued a Medicare Claims Processing Manual to the Fiscal Intermediaries and to the Carriers (including the DME MACs.) Chapter 1, Section 80 - Carrier and FI Claims Processing Timeliness, provides at subsection 80.2.1.2 the definitions for electronic and paper claims:

> An "electronic claim" is a claim submitted via central processing unit (CPU) to CPU transmission, tape, direct data entry, direct wire, or personal computer upload or download.
>
> A "paper claim" is submitted and received on paper, including fax print-outs. This also includes a claim that the contractor receives on paper and then reads electronically with OCR technology.

37. Medicare's contractors process millions of claims each week. According to "2010 CMS Statistics" published by the U.S. Department of Health and Human Services, in fiscal year 2009, the carriers processed 999.5 million claims. "2010 CMS Statistics" reports that in fiscal year 2009, $503.9 billion in Medicare claims were processed. Given the brief time carriers have to process a monumental volume of claims, the "pay and chase" system relies on the honesty of providers and the accuracy of the claims they submit.

38. The Chief Counsel to the Inspector General for the Department of Health and Human Services has explained:

> Federal health care programs operate under a 'pay and chase' model. Government contractors that process and pay claims for reimbursement generally presume that qualified providers submit claims for medically necessary items or services. The majority of claims are submitted electronically, processed based on predictable edits applied to representations on the claim, and paid claim by claim with limited verification that the services were actually provided or were necessary. Additional analysis is needed to determine whether a series of claims, each of which may appear legitimate by itself, demonstrates fraud or abuse when taken together. The U.S. government generally identifies abusive billings through retrospective analysis after it has paid the claims. Although the payment process includes some front-end safeguards, criminals are increasingly sophisticated in detecting and circumventing those measures.
>
> Lewis Morris, "Combating Fraud in Health Care: An Essential Component of Any Cost Containment Strategy", Health Affairs vol. 28, No. 5 (Oct. 2009), pp. 1351-1356

39. Early on, KCI had a choice about how to submit its claims to Medicare. KCI could either submit "paper claims" to be processed manually, or "electronic claims." At roughly the same time that Medicare started the transition from DEMRCs to DMACs, some of its billing procedures were changed. One of the billing procedures that changed was how claims could be submitted. It became mandatory for large suppliers, including KCI, to submit all claims electronically. Medicare would no longer accept "paper claims" from those suppliers. The predictable significant increase in the number of "electronic claims" that would be submitted pursuant to this change greatly increased the potential vulnerability of "pay and chase" to fraud. Because of the requirement that Medicare must pay claims submitted electronically within fourteen (14) days of receipt of the claim, the Medicare system became even more reliant on a presumption that "qualified providers submit claims for medically necessary items or services" – that is, reliant on straightforward honesty by those submitting claims.

40. To protect, in part, against abuse of the "pay and chase" approach for fraudulent purposes, the Office of Inspector General of the U.S. Department of Health and Human Services has the authority to impose a penalty of $10,000 (or as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, and as amended by the Debt Collection Improvement Act of 1996) for each wrongful act when it determines that a provider has knowingly presented a claim

for payment to Medicare that the provider knew was not covered. See, 42 C.F.R. § 1003.102 and 103(a)(2).

41. KCI understood how Medicare's "pay and chase" payment system operated. KCI took advantage of the "pay and chase" payment system when it submitted a variety of false claims to the DMERCs and later to the DME MACs for reimbursement knowing that the reimbursement requests would not be verified before payment was made as the DMERCs/DME MACs relied upon the honesty and integrity of the suppliers submitting claims for reimbursement. Each of KCI's false claims will be more thoroughly explained below.

B. LOCAL MEDICAL REVIEW POLICY (LMRPs) and LOCAL COVERAGE DETERMINATIONS (LCDs)

42. The U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) promulgate federal regulations and National Coverage Determinations (NCDs) upon which Medicare Fiscal Intermediaries/Carriers rely to make coverage determinations for claims for medical services and items provided to beneficiaries. HHS adopts NCDs to exclude certain items and services from coverage on a national level that are not reasonable and necessary under HHS' interpretation of the Medicare Act. Federal regulations and NCDs are binding on all Medicare Fiscal Intermediaries/Carriers nationwide. 42 U.S.C. § 1395ff(f)(1)(B).

43. Absent a NCD, Fiscal Intermediaries/Carriers and their divisions such as the DMERCs, as agents of the federal government, are authorized to establish Local Medical Review Policies (LMRPs), which were later supplanted by Local Coverage Determinations (LCDs).

44. When an item of durable medical equipment is not governed by a NCD, each regional DMERC issues an LMRP identifying indications and limitations of coverage, as well as terms for the continuation and termination of coverage. See 42 U.S.C. § 1395kk-1(a)(4).

45. LMRPs establish specific criteria for initial and continued coverage of a service or item. LMRPs also identify circumstances under which Medicare will deny coverage for a service or item as not reasonable and necessary. See 42 C.F.R. § 400.202.

46. The first LMRPs for Negative Pressure Wound Therapy (NPWT) were issued by the DMERCs effective October 1, 2000.

47. The NPWT LMRPs were converted to LCDs in the fall of 2005 and early 2006. These LCDs remained effective during all relevant times covered by this action.

48. The Social Security Act defines Local Coverage Determination as:

> B) Definition of local coverage determination - For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or

> service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A). 42 U.S.C. § 1395ff (f)(2)(B).

49. Each of the DMERCs (now the DME MACs) publishes and provides LCDs to the providers and suppliers in its region.

50. CMS publishes a Medicare Program Integrity Manual. It instructs the Carriers that when determining whether a treatment is "reasonable and necessary" under section 1395(y)(a)(1)(A), they may apply the so-called "reasonably feasible and medically appropriate" least costly alternative policy. (Chapter 13.4.A) (Rev. 71, April 9, 2004). Application of this policy is mandatory with respect to durable medical equipment. Chapter 13 of the Medicare Program Integrity Manual provides the following detailed information regarding LCDs:

> **13.1.3 - Local Coverage Determinations (LCDs)**
> **(Rev. 165, Issued: 10-06-06, Effective: 09-11-06, Implementation: 10-26-06)**
> Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term "local coverage determination" (LCD). An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist of only "reasonable and necessary" information, while LMRPs may also contain benefit category and statutory exclusion provisions.

51. Medicare does not pay for medical treatments that are not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A), 42 C.F.R. § 411.15(k). The Medicare

Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services states that "[a]lthough an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member." The Medicare Benefit Policy Manual, Chapter 15 (Rev. 120, 01-29-10) also states as follows:

> Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness: 1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment? 2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care? 3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

52. The DME MACs apply the constraints of the LCD to each claim submitted by medical providers and suppliers such as KCI to determine whether to pay the claim or to deny the claim as not "reasonable and necessary" according to the limitations set forth in the LCD, and as mandated by the overarching provisions of 42 U.S.C. § 1395y(a)(1)(A).

53. The initial LMRP for Negative Pressure Wound Therapy (NPWT) systems such as KCI's VAC became effective on October 1, 2000 and was the culmination of extensive debate and negotiation between the DMERCs and KCI over

the indications and limitations of Medicare coverage for NPWT as well as the conditions for continuation and termination of coverage. At the time of the negotiations described herein, KCI had developed the first and only NPWT system available and was the sole supplier of the VAC and related supplies utilized in NPWT.

54. The NPWT LMRP established what each DMERC believed was the congressional intent of the prohibition in 42 U.S.C. § 1395y(a)(1)(A) that Medicare will only pay for items or services deemed medically necessary.

55. KCI provides VAC therapy not only for patients whose health insurance coverage is provided by Medicare (or other governmental health care agencies), but also for patients whose health insurance coverage is provided by private insurers.

56. KCI knows from experience that virtually all health insurers in the private market refuse to pay for VAC therapy unless their insured patient obtains pre-authorization from the insurer before VAC therapy begins. The reimbursement rates identified above are much more expensive than traditional treatment methods for wounds, and the private insurance companies use pre-authorization processes to scrutinize whether VAC therapy is truly medically necessary and cost-effective. It is a very effective procedure for preventing over-utilization of an expensive therapy, thereby containing costs. That same concern is expressed in the Medicare Benefit Policy Manual language quoted at ¶53.

57. A pre-authorization process can be slow and can include administrative expense. The investment of time and administrative expense might deter some health care providers (doctors, skilled nursing facilities, etc.) from recommending the use of VAC therapy. It might also deter patients from using VAC therapy, if they are unwilling to await the verdict from a pre-authorization process.

58. To get VAC treatment approved by Medicare for reimbursement using the "pay and chase" approach, rather than a pre-authorization process similar to what it was experiencing with private insurers, KCI made a series of promises to HCFA. The DMERCs' Medical Directors wrote their LMRPs to hold KCI to those promises. The foundational commitment that underlies the LMRPs' WOPD requirements is KCI's promise that VAC therapy would not be delivered to the patient before KCI had received a complete and accurate Detailed Written Order.

59. All four regional DMERCs developed identical requirements for NPWT and VACs including the WOPD requirements in their respective versions of the NPWT LMRP, making the indications and limitations of coverage, continuation and termination for the VAC uniform nationwide. The current NPWT LCD has been and remains uniform among the four regional DME MACs.

60. A medical supplier or provider that disagrees with the terms of an LCD or an NCD may challenge all or any part thereof through an administrative process set forth in 42 C.F.R. § 426 et seq.

61. KCI has never invoked the administrative process to challenge all or any portion of the NPWT LCD or the former LMRP during Godecke's employment, and to the best of her knowledge, information and belief, KCI has not done so to date.

C. THE REQUIREMENT TO HAVE WRITTEN ORDERS PRIOR TO DELIVERY OF VAC THERAPY

62. To address the concerns about medical necessity expressed in the Medicare Benefit Policy Manual language quoted at ¶53, without impairing the availability of a therapy in circumstances when it might be truly medically necessary, Medicare can require a detailed written order.

63. Congress vested The Secretary of HHS with the authority to require, for specified covered DME items, including as KCI's VAC, that payment for the item may be made under the Medicare statute only if a physician has communicated to the supplier, *before delivery* of the item, a written order for the item. 42 U.S.C. § 1395m(a)(11)(B). This addresses the cost proportionality concern expressed in the Medicare Benefit Policy Manual language quoted at ¶53.

64. The Secretary of HHS promulgated a regulation pursuant to the authority granted in 42 U.S.C. § 1395m(a)(1)(B) which provides "As a requirement for payment, CMS may determine through carrier instructions, or carriers may determine that an item" of durable medical equipment requires a written physician order before delivery of the item. 42 C.F.R. § 410.38(g).

65. CMS, pursuant to authority delegated to it by The Secretary of HHS, has required that suppliers of all Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items must obtain a "Detailed Written Order" before submitting a bill to Medicare, pursuant to the Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3.

66. Detailed Written Orders may take the form of a photocopy, facsimile image, electronically maintained image or an original pen-and-ink document.

67. A Detailed Written Order for rented DMEPOS items such as KCI's VAC must contain information satisfying each of the following six elements:

(a) beneficiary name;

(b) detailed description of item either a narrative description or brand name/model number;

(c) all options and accessories that will be billed separately or which require an upgraded code;

(d) signature of the treating physician and the date the order is signed;

(e) initial date of need or start date; and

(f) the length of need.

68. The Medicare Program Integrity Manual provides that "[s]omeone other than the treating physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement." Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3.

69. In addition, the Medicare Program Integrity Manual identifies certain DMEPOS items for which a supplier must receive a Detailed Written Order ***prior to delivery*** of the item ("Written Order Prior to Delivery" or "WOPD"). Negative pressure wound therapy pumps, including KCI's VAC, are among the few items identified by Medicare that require the Detailed Written Order ***prior to delivery*** of the item, in order to qualify for Medicare reimbursement. Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3.1. KCI refers to this requirement in-house as a "prior written order."

70. Thus, for KCI's VAC therapy to qualify for Medicare reimbursement, KCI must obtain all six elements of a Detailed Written Order (identified in ¶68), ***prior to delivery*** of the VAC to a patient. (Accordingly, in this case, the phrases "Detailed Written Order," "Detailed Written Order Prior to Delivery," "Written Order Prior to Delivery" and "Written Order" all address the same VAC-related items that KCI is *required* to obtain before delivering a VAC to a Medicare patient. Relator will use "Written Order Prior to Delivery" or "WOPD" to reference these requirements.)

71. A complete WOPD includes an expiration or end date addressing "the length of need" for the VAC therapy. If VAC therapy continues beyond the initial "length of need," a new WOPD is required before delivery of VAC therapy for the new time period. In other words, for each "length of need," a new WOPD is required to continue the therapy, and the supplier must have such order on hand before

delivering the next period of therapy. Otherwise, VAC therapy that continues beyond the initial "length of need" will not be eligible for Medicare reimbursement.

72. The requirement of obtaining a Detailed Written Order addressing all six elements identified above, prior to delivery of the VAC, has been in the Medicare Program Integrity Manual since at least 2000, when KCI was first authorized to bill Medicare.

73. If KCI does not have all six elements required for a complete Detailed Written Order *prior* to delivery of a KCI VAC, the Medicare Program Integrity Manual requires the DME MAC to deny the claim as statutorily non-covered or as not meeting the benefit category. The effect of a claim being denied as statutorily non-covered or as not meeting the benefit category is that the denial is not appealable. Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3, §5.2.3.1.

74. In addition to the requirement for a Detailed Written Order Prior To Delivery of a VAC as mandated by the Medicare Program Integrity Manual, the NPWT LMRPs/LCDs themselves have always required the same. The initial NPWT LMRP stated under the Documentation section:

> A written order for the negative pressure wound therapy pump and supplies must be signed and dated by the treating physician and obtained by the supplier prior to delivery of the item. The order must be kept on file by the supplier.

D. THE MEANING AND PURPOSE OF BILLING MODIFIERS IN THE MEDICARE "PAY AND CHASE" REIMBURSEMENT SYSTEM

75. The electronic claims processing systems developed by the Medicare Administrative Contractors allow providers and suppliers to communicate with the DME MACs regarding billing by including alphanumeric billing codes on the Medicare claim forms. Central to this process are codes called "HCPCS" - the Health Care Common Procedure Coding System.

76. The HCPCS codes include certain codes known as "modifiers." Some billing modifiers are given unique instructions for use depending on which Medicare benefit category applies to the particular service or item. A billing modifier facilitates faster processing of electronic claims by Medicare, because it signals a commonly understood summary of pertinent facts regarding required elements of the claims to which the modifier applies.

77. Beginning with the first NPWT LMRP, which became effective October 1, 2000, to the present, the NPWT LMRPs (now LCDs) have provided for the use of certain billing modifiers.

78. HHS deemed these regulations and this use of the modifiers as critically important because they helped ensure that only proper medically necessary usages were reimbursed and, therefore, HHS would not be paying for unnecessary usages. At the same time, it would help Medicare process claims quickly. The proper application of a modifier served as a deterrent to illegal billing and as a necessary

check on provider conduct as KCI was well aware. If KCI used the modifiers as Medicare required, KCI would be informing Medicare and other governmental providers, in a summary, yet effective, manner whether the United States should or should not pay a specific claim

1. THE GZ AND GA MODIFIERS

79. On April 26, 2001, HHS issued Program Memorandum Carriers Transmittal B01-30 in which the modifiers GY and GZ were introduced. The transmittal stated, "[t]he new modifiers, GY and GZ, must be used when a specific code is available but the provider or supplier wants to indicate that the item or service is not covered or is not reasonable and necessary."

80. On March 27, 2002, HHS issued Program Memorandum Carriers Transmittal B-02-020 in which it said "[t]he new GZ modifier must be used when suppliers want to indicate that they expect that Medicare will deny an item or supply as not reasonable and necessary and they have not had an Advance Beneficiary Notification (ABN) signed by the beneficiary. . . The GA modifier must be used when suppliers want to indicate that they expect that Medicare will deny an item or supply as not reasonable and necessary and they do have on file an ABN signed by the beneficiary."

81. The CMS Manual System on December 22, 2006, defined the GZ modifier as the "Item or Service not Reasonable and Necessary (expected to be denied as not reasonable and necessary, no ABN on file)" and the GA modifier as

"Waiver of Liability (expected to be denied as not reasonable and necessary, ABN on file)."

82. Although a provider like KCI may submit claims for costs it knows to be presumptively non-reimbursable, it must do so openly and honestly, describing the claims accurately while challenging the presumption and seeking reimbursement. Medicare created the GZ and GA modifiers partly for this purpose.

83. Similarly, KCI had the ability to challenge through a patient receiving VAC treatment, the appropriateness of any provision of the LMRP as policy. CMS Ruling No. 01-01, Sept. 28, 2001. KCI never exercised this option.

2. THE KX MODIFIER

84. Near the beginning of each of the initial NPWT LMRPs, the DMERCs included the following language with respect to the use of a billing modifier:

> HCPCS Modifier:
>
> ZX - Specific requirements found in the Documentation section of this medical policy have been met, and evidence of this is available in the supplier's record.

85. For example, a copy of the initial NPWT LMRP published by Palmetto Government Benefits Administrators, LLC, the Region C DMERC in October 2000, is attached hereto as EXHIBIT 1 at Page 1.

86. Near the end of each of the initial NPWT LMRPs, the DMERCs included the following language with respect to the use of a billing modifier:

> If all of the conditions are met under criteria A1 - A4, B1 - B2 and C1 - C2 in the Coverage and Payment Rules section, a ZX modifier is to be added to the HCPCS codes on each month's claims for initial and continued use of NPWT equipment and supplies.
>
> The ZX modifier **must not be used** if all of the policy's coverage criteria for initial and continued use have not been met. (Emphasis in original.)
>
> The ZX modifier **must not be used** if any of the conditions listed in the Coverage and Payment Rules section under "Other Exclusions from Coverage" are present. (Emphasis in original.)
>
> The ZX modifier **must not be used** if any of the situations D1 - D5 (listed in the Coverage and Payment Rules section under "When Coverage Ends") are present. (Emphasis in original.)

87. CMS replaced the ZX modifier with the KX modifier, effective July 1, 2002. The only difference was that the modifier went from a temporary designation (ZX) to a permanent designation (KX). None of the listed prohibitions in the NPWT LMRP were changed.

88. The NPWT LMRPs were occasionally revised by the DMERCs between 2000 and the present. However, the fundamental instructions for use of the KX modifier have remained consistent through all revisions, i.e., the modifier may only be attached to a claim when all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LMRP/LCD have been met and the claim is payable as submitted.

89. The DME MACs rely upon KCI's integrity to add the KX modifier to its claims to honestly communicate that *no reason exists to deny the claim* as "not reasonable and necessary" and that the claim represents a proper call upon the public fisc.

90. During Relator's employment at KCI, the KX modifier became known "in-house" as the "Pay Me" modifier.

91. The Office of the Inspector General for the Department of Health and Human Services provided the following information and instruction about the proper use of the KX modifier:

> "By adding the KX modifier the supplier attests that the specific required documentation . . . is on file at the supplier before submitting the claim to the DME MAC."

"Review of Medicare Payments for Selected Durable Medical Equipment Claims with the KX Modifier for Calendar Year 2006" (A-04-08-04020), January 4, 2010.

92. As early as 1999, before KCI's VAC was approved for Medicare coverage, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) warned that misuse of the KX modifier's predecessor, the ZX modifier, could result in false claims. OIG's "Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry" published in the Federal Register on July 6, 1999, warned that:

> The DMEPOS supplier should create internal mechanisms to ensure the proper use of the ZX modifier. **Improper use of the modifier may result in the submission of false claims.** The OIG recommends that the DMEPOS suppliers written policies and procedures address the DMEPOS suppliers protocol for using the ZX modifier. (FN 118) FN 118 - See relevant DMERC supplier manual(s) for guidance on proper use. (Emphasis added.)

93. On January 22, 2002, a Program Memorandum was issued by the DMERCs entitled "New Permanent Modifier for Specific Required Documentation on File." The policy stated:

> Effective for claim submission dates on and after July 1, 2002, DMERCs must discontinue use of the "ZX" modifier and use the following new level II national modifier: "KX": Specific Documentation on File.
>
> * * *
>
> Advise providers and suppliers that their use of this modifier constitutes a statement to the effect that they actually have the documentation on file that the policy requires for the particular item or service.

94. On April 25, 2002, CMS issued ¶ 152.619, Program Memorandum Transmittal No. B-02-026, which repeated the requirements regarding the new KX modifier as defined in the Program Memorandum issued on January 22, 2002.

95. Tricenturion, the Fiscal Intermediary/Carrier for DMERC Region A, in its 2002 Local Medical Review Policy (LMRP) stated in the "General Information - Document Requirements" section that:

> Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been

> furnished such information as may be necessary in order to determine the amounts due such provider." (42 U.S.C. section 1395(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

96. Tricenturion, the Fiscal Intermediary/Carrier for DMERC Region A, in its 2005 Local Coverage Determination (LCD) stated in the "Coding Information" section that KX meant that specific required documentation was on file, and further stated in the documentation requirements section that Suppliers *must* add a KX modifier to a code only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met.

97. The Fiscal Intermediaries/Carriers in the other regions had policies that matched the above-stated Tricenturion policy.

98. In approximately December 2007, DMERC Region B published a newsletter that was distributed to Durable Medical Equipment suppliers. The topic was "Understanding the Usage of the KX Modifier." The newsletter stated:

> The submission of the KX modifier on a claim is used to convey to the DME MAC and the PSC that 'specific' requirements found in the documentation section of the LCD have been met **and** the documentation is available within the supplier's records. (Emphasis in the original)
>
> Suppliers should refer to each individual medical policy to verify coverage criteria for an item and/or service prior to appending the KX modifier to their claims. **Inappropriate**

> **use of the KX modifier (i.e., coverage criteria not being met) is deemed fraudulent**. (emphasis added)

99. National Government Services, Inc., the Fiscal Intermediary/Carrier for DMERC Region B, in its 2009 Local Coverage Determination (LCD) defined the KX modifier as "requirements specified in the medical policy have been met." It went on to state that "[s]uppliers must add a KX modifier to a code only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met."

3. THE EY MODIFIER

100. The DMERCs revised the NPWT LMRP in 2003, by re-wording the requirements for the Detailed Written Order and adding a new billing modifier, EY, specifically for use when a NPWT item was delivered before a signed written order had been received by the supplier. Effective April 1, 2003, the NPWT LMRP provided the following language in the Indications and Limitations of Coverage and/or Medical Necessity section:

> For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. **If the supplier delivers the item prior to receipt of a written order, it will be denied as non-covered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained.** If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage. (Emphasis added.)

101. The newly revised NPWT LMRP, effective April 1, 2003, further identified the new HCPCS modifier as "EY – No physician or other health care provider order for this item or service." In addition, the new revision provided the following in the Documentation Requirements section:

> An order for each item billed must be signed **and dated by the treating physician**, kept on file by the supplier, and made available to the DMERC upon request. **Items delivered before a signed written order has been received by the supplier must be submitted with an EY modifier attached to each affected HCPCS code.** (Emphasis added.)

102. Every NPWT LMRP/LCD and NPWT Policy Article issued after April 2003 contained virtually the same language requiring receipt of a Detailed Written Order prior to delivery of the VAC and requiring KCI to bill the claim with the EY modifier **if the unit was delivered before all elements required in a Detailed Written Order had been obtained**.

103. The version of the NPWT LCD, effective 1/1/11, provides in the Documentation Requirements section:

> An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

104. The version of the NPWT Policy Article, effective 1/1/11, provides the following instruction under the Non-Medical Necessity Coverage and Payment Rules section:

> For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as non-covered. If the written order is not obtained prior to delivery, **payment will not be made for that item even if a written order is subsequently obtained**. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage. (Emphasis Added.)

105. DMERC Region C updated its LMRP No. L5008 in 2003, to include the new EY Modifier, which specifically addressed circumstances in which a doctor's written order was not received by the supplier before the DME was delivered to the patient, saying

> An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items delivered before a signed written order has been received by the supplier **must be submitted with an EY modifier added to each affected HCPCS code**. (Emphasis added.)

106. In its Summer 2003 DMERC Medicare Advisory, at page 54, DMERC Region C reminded DME suppliers about the new EY Modifier, making the following points:

> Effective for dates of service on or after January 1, 2003, a new modifier (EY) was created for use when billing claims for items provided without a physician's order.
>
> For those claim lines where the item does not have an order, the modifier EY must be appended.
>
> For claims where there is no order for any of the items billed, suppliers should use "No Physician" for the ordering physician's name in Field 17 and use the surrogate UPIN OTH000 in Field 17a. Modifier EY is then appended to the procedure code for each item. Claim lines for items without a physician's order, as indicated by the use of modifier EY, will be denied as not medically necessary…

107. As previously noted, the requirements for Medicare payment of NPWT have been consistent among all four DMERC regions.

108. Although a provider like KCI may submit claims for costs it knows to be presumptively non-reimbursable, it must do so openly and honestly, describing the claims accurately while challenging the presumption and seeking reimbursement. Use of the EY Modifier was required by Medicare partly for this purpose.

109. As with the other billing modifiers, KCI had the ability to challenge through a patient receiving VAC treatment, the appropriateness of any provision of the LMRP as policy. CMS Ruling No. 01-01, Sept. 28, 2001. KCI never exercised this option.

VI.
KCI EXPECTATIONS AND FOLLOW UP

A. STAFF PERFORMANCE

110. The procedures for delivering a VAC to a patient began when a physician, nurse, or other health care provider contacted KCI to request delivery of a VAC to a patient.

111. When a VAC delivery request was received by the KCI staff person, it was noted in KCI's Ship Pending Database, and a unique Rental Order Entry (ROE) number was assigned to that VAC delivery request.

112. Notice of the new VAC delivery request, and the ROE assigned to it, was sent electronically to Customer Service Representatives (CSRs) who work in the Ship Pending Departments of KCI's various offices.

113. Because private insurers require pre-authorization for a VAC in order to qualify the VAC for payment by those insurers, the process for handling the delivery of VACs to Medicare beneficiaries was somewhat different from the process for delivery of a VAC to a patient whose treatment is funded by private insurance. KCI had groups of CSRs dedicated to each market.

114. If the patient was a Medicare beneficiary, the VAC delivery request and its ROE would go to a group of CSRs specifically assigned to serve Medicare patients. This made it easier for the CSRs to track payor requirements consistently.

115. It was the responsibility of the CSR to collect the documentation necessary for the VAC to be eligible for Medicare reimbursement.

116. It was also the responsibility of the CSR to document, in the Ship Pending Database, the progress of acquiring the necessary documentation to qualify

the VAC for Medicare reimbursement. Whenever a piece of the required documentation was acquired, the CSR would make an entry to that effect in KCI's Ship Pending Database.

117. Once all the information required for the Detailed Written Order Prior to Delivery was obtained, the CSRs are able to accomplish their primary objective, which is to "CAVE" the cycle for billing. CAVE was an in-house acronym meaning that the Fast Form RX, or at least the portion containing the elements of the Detailed Written Order Prior to Delivery, was "Complete, Accurate, Verifiable and Eligible for billing."

118. When the doctor or other health care provider sent a written order to KCI, complete with all six elements required for a complete and valid WOPD, the VAC could be released for delivery to the patient. With the initial placement of the VAC, if all requirements for billing Medicare were satisfied, including complete satisfaction of the WOPD requirements prior to delivery of the VAC, a claim could be submitted to Medicare and would be eligible for billing with a KX modifier, and the EY modifier would not be required.

B. INFORMATION SYSTEMS, DATABASES AND REPORTS.

119. To track its progress in obtaining all information required to qualify a VAC for reimbursement by Medicare, KCI developed several reporting tools as part of its inventory management and billing/accounting information systems.

120. The information system for tracking VAC deliveries was called the Ship Pending Database.

121. Various management and tracking reports could be generated from KCI's inventory management and billing/accounting management information systems. Examples include Follow Up Reports and Forced Pickup Reports.

122. Each of these reports included information that specifically identified each deficiency that prevented KCI from the submitting a claim to Medicare. Whether it was one of the six elements required for a WOPD or some other requirement that prevented billing Medicare, each deficiency was specifically identified in these reports. Thus, each required WOPD element described in ¶68 was listed separately if it had not yet been received by KCI.

123. Another KCI report, the Unbilled by Status Code Report, listed approximately sixty items that could in some way prevent KCI from submitting a valid claim to Medicare. Included among these sixty items were the six elements required for a WOPD. Each such item was assigned a status code, enabling a reader of the report to know exactly what prevented the filing of a specific claim. Along with the other items that might prevent KCI from submitting a valid claim, each required element of a WOPD had its own status code. (For example, Status Code No. 22 was denominated "Rx missing + other problems," and Status Code No. 23 was denominated "Rx missing only.") Any missing WOPD element would be identified on this report.

124. The Ship Pending Database also included entries showing the date each VAC was released for delivery, meaning that KCI had determined that all WOPD requirements had been satisfied and that KCI was in possession of all six WOPD elements. KCI delivered VACs within a few short hours after the release decision was made.

125. By comparing the release date of a VAC with the dates shown for receipt of required pieces of documentation, one could easily determine whether a VAC had been delivered prior to receipt by KCI of all elements required for a WOPD.

126. KCI also developed a report called the "Forced Pickup Report." When a document required for submitting a bill had not been obtained within one month after the delivery of a VAC, KCI placed that order (ROE) on the Forced Pickup Report. The Forced Pickup Report was published two times per week for both KCI management and the field staff (sales force, service centers, and nurses). The first such publication each week was actually known as the "Preliminary Forced Pickup Report." Its purpose was to signal a "last chance" for KCI staff to gather all required documentation, because if a VAC was picked up by KCI, the CSR and field staff, who were paid on a commission basis, would not get paid for that VAC. The second publication each week was the list of patients whose VACs KCI had ordered to be picked up because KCI's staff had been unable to obtain the needed documents - the Forced Pickup Report.

127. Both the Preliminary Forced Pickup Report and the Forced Pickup Report identified each piece of missing documentation specifically, including any missing elements of a Detailed Written Order that KCI needed before delivery in order to bill the claim. KCI staff could look at these reports and, without seeking information from any other source, know exactly which elements of a WOPD had not yet been obtained.

128. Separate and apart from the delivery-focused Ship Pending Database, KCI maintained a "MicroMD" database to track billing and payment. (This information system has evolved over time and is known to some as "MicroMD.") It is used to manage information about when bills and claims are submitted to Medicare and other payors, when payments are received, amounts of each payment, and when claims are denied.

129. Although the Ship Pending Database and the MicroMD database are separate systems, they both use the same ROE numbers as identifiers for the inter-related business activities addressed in their respective information technology environments. That is, in the Ship Pending Database, the ROE identifies inventory management (receipt of an order for a VAC, tracking documentation progress, and delivery of that VAC to the customer/patient), while the same ROE is used to track billing and payment in the MicroMD system for the same VAC.

130. Relator Godecke knows about the relationship between the Ship Pending Database and MicroMD information systems because her duties at KCI required her to work with both systems.

C. FORMS AND CHECKLISTS

131. In addition to the Ship Pending Database and reports generated from it, KCI developed form checklists to simplify the tasks required of CSRs and their supervisors. In 2003, a form used by KCI was called an Initial Statement of Provider (ISOP). See attached Exhibit 2. The ISOP had a section requiring the doctor to sign the order, but it also included in Section II and III the requirements that KCI needed to confirm medical necessity. The WOPD requirements were met by filling out Section IV, which included a data field for each of the six elements required for a complete Written Order Prior to Delivery, if it was signed and dated by the doctor. Indeed, the heading of Section IV of the ISOP read,

> "Physician's Prescription - The physician must sign and date the prescription prior to delivery of the V.A.C.
>
> Physician's Signature: Attests to the validity and accuracy of information in this Sec. iv and prescribes the V.A.C. pump for the named patient." (Emphasis added.)

132. In 2004, KCI developed a form known in-house as the "Fast Form RX" which replaced the ISOP form. Exhibit 3. The Fast Form Rx contained a section

called the "Physician's Attestation Box," where information about satisfaction of all six elements of the Detailed Written Order Prior to Delivery was to be inserted.

VII.
KCI DID NOT ADHERE TO ITS OWN PROCEDURES OR TO MEDICARE REQUIREMENTS

133. Once a physician or medical provider prescribes negative pressure wound therapy for a patient, KCI management puts immense pressure upon its managers and employees to deliver the VAC and its supplies to the patient as quickly as possible. Management and staff job reviews and raises were tied to fast VAC deliveries. Bonuses were also tied to fast VAC deliveries. CSRs received a quarterly productivity bonus based, in part, on the amount of time between each VAC order and the authorization for release of the device for delivery.

134. Unfortunately, KCI did not follow its own procedures or the Medicare rules. Often getting a completed WOPD was not quick, therefore holding up the delivery of the VAC, creating a financial and customer service problem. The patient wanted and needed the VAC immediately, and KCI wanted to accommodate the doctors and the patients so that doctors would continue to prescribe the VAC and so that KCI could be paid as promptly as possible. The solution for KCI was to deliver the VAC without a completed WOPD.

135. The Preliminary Forced Pick Up Report and the Forced Pick Up Report could have been very effective tools for assuring compliance with the Medicare WOPD requirements. In practice, however, many exceptions were authorized by KCI

management, allowing CSRs and field staff to release a VAC, which would make the claim seem billable per KCI procedures, even though Medicare's WOPD requirements had not been satisfied. KCI sales executives could – and very often did – override KCI procedures that would cancel staff commissions for VACs delivered before all elements required for a complete and valid WOPD were in KCI's possession, merely by making a phone call.

136. Because billing was usually done at the end of the month or the first cycle of VAC treatment, KCI recognized that it had 30 days to obtain the completed written order before it had to bill Medicare. If the detailed written order was obtained prior to billing, KCI billed Medicare with the KX modifier, not the EY modifier, even though the written order had NOT been obtained prior to delivery of the VAC as required by the LCD. Nowhere in the claim process was KCI required to inform Medicare exactly what date the written order had been received. So, unless Medicare audited a claim, and knew exactly what to look for and where to look, KCI knew it could cheat the system.

137. In addition to the three KCI offices that released VACs, there was a lot of rule bending in the field. Some sales representatives carried VACs in their cars, that records showed to be officially be in Service Center inventory, which could be given to a patient immediately. Inventories of VACs were kept in hospitals so that the patient could go home with one, often ahead of the paperwork.

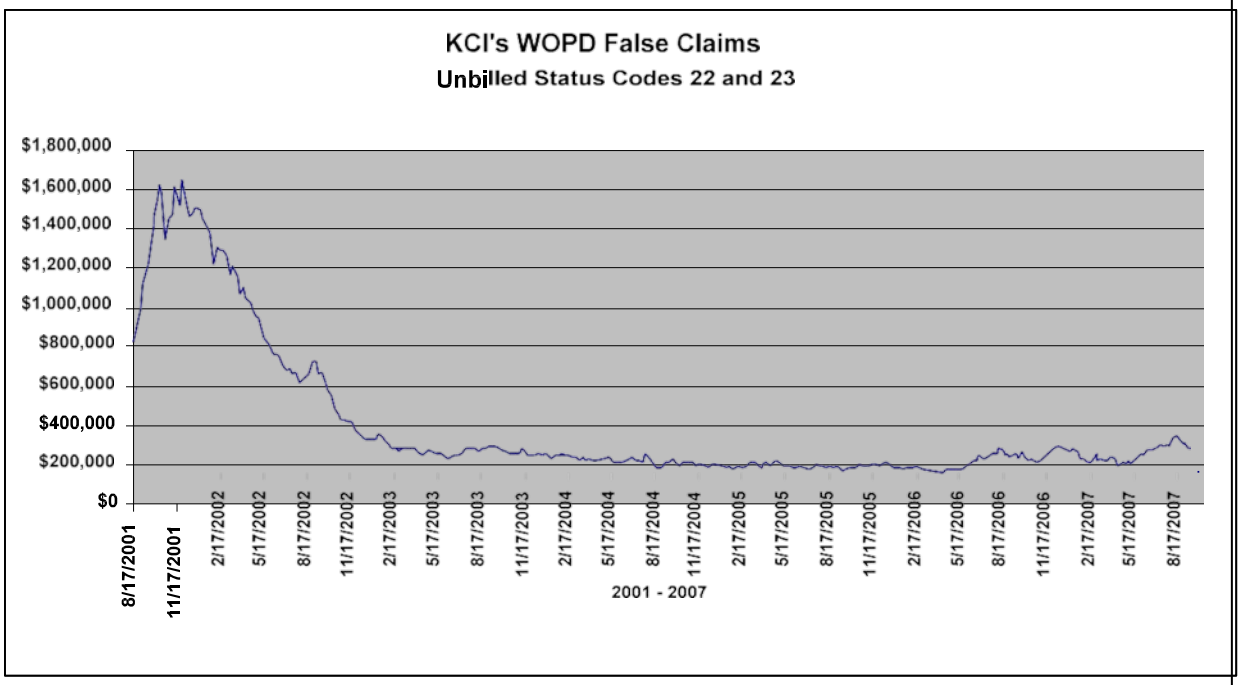
VIII.
KCI SUBMITTED FALSE CLAIMS

138. KCI submitted False Claims, because it submitted many claims to Medicare for VACs that were delivered before KCI had all required WOPD elements in its possession, and KCI did not add the EY Modifier to the documentation for those claims. Moreover, as explained below, even if use of the EY Modifier were not an issue, KCI certified on the CMS 1500 Forms it submitted with each claim, that it was complying with all applicable laws, when in fact KCI was not complying. KCI management fully understood that KCI was not allowed to deliver VACs until all WOPD elements were in its possession, but delivered VACs when it did not have all WOPDS elements in its possession, and submitted claims to Medicare for those VACs.

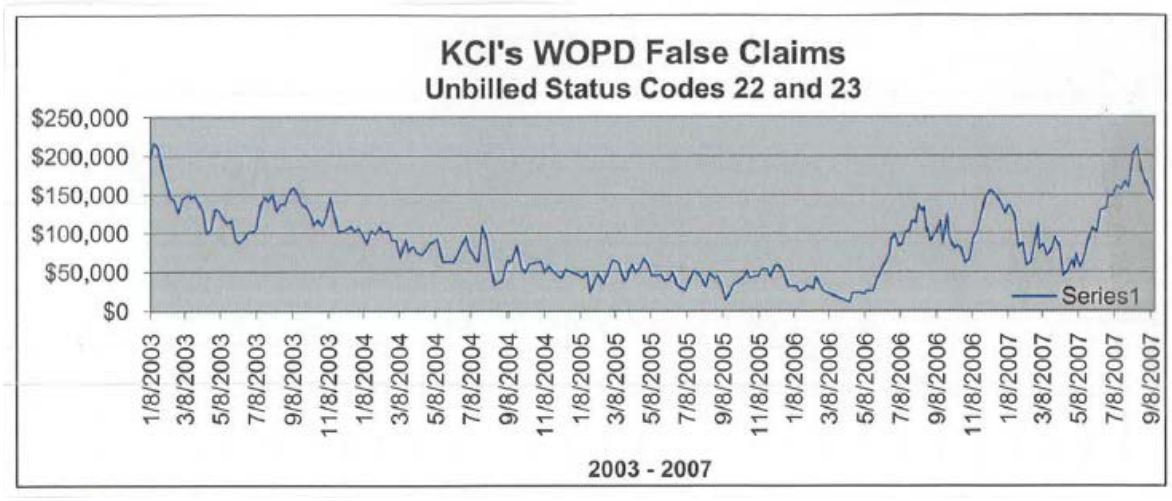
A. KCI DELIVERED MANY VACs BEFORE HAVING ALL WOPD ELEMENTS IN ITS POSSESSION

139. In 2001 and 2002, KCI had placed large numbers of VACs without first obtaining a Detailed Written Order. In 2002, KCI began to increase its efforts to obtain qualifying Detailed Written Orders before delivery of its VACs.

140. The chart below, showing the reduction in Unbilled Status Code 22 (Rx missing + other problems) and Unbilled Status Code 23 (Rx missing only) in 2002, demonstrates this effort.



141. In mid-2006, KCI began an aggressive campaign to place VACs more quickly to alleviate doctor and home health agency dissatisfaction with KCI's customer service. This campaign resulted in more VACs being placed on patients without a prior Detailed Written Order. This is shown in the following chart of Status Code 22 and 23 volumes between 2003 and 2007.



142. Based upon a Follow Up Report dated July 18, 2006, KCI delivered 92 VACs to patients that day, all of which needed additional information before all elements required for a complete and valid Detailed Written Order Prior to Delivery had been received. Thus, none of the claims for those VACs could be submitted to Medicare with an expectation of payment. That Follow Up Report showed that eight of those orders specifically lacked a qualifying prescription or Rx (i.e., a Detailed Written Order) before delivery of the units to the patients. That Follow Up Report also showed that all 92 of those VACs were delivered, even though the KCI systems showed that at least one of the required WOPD elements was not yet in KCI's possession

143. Relator Godecke knows first-hand that KCI delivered VACs to patients before all of the WOPD requirements had been satisfied, because she observed it while training and supervising groups of employees in the Montana office who worked as CSRs in Godecke's department at various times beginning in approximately 2004 and continuing off and on through Godecke's termination in September 2007. She was informed by her CSRs of exceptions granted by KCI management so that her CSRs could release VACs for delivery. She communicated with KCI management herself about such exceptions. And she saw the exceptions noted on Forced Pickup Reports.

144. Godecke also knows that KCI delivered VACs to patients before all of the WOPD requirements had been satisfied, because she was involved in creating systems and processes specifically for following up on orders for VACs that had been delivered by KCI without having all the elements required to satisfy requirements for a Detailed Written Order Prior to Delivery in its possession. Godecke knew from management explanations of those duties that KCI management knew the Medicare requirements for WOPD, and knew that Medicare would not pay for those VACs if Medicare knew that those VACs had been delivered before the WOPD requirements were fully satisfied, and knew that the missing WOPD elements had to be obtained quickly in order to mask the fact that VACs were delivered without all of those elements in hand, so KCI management set up tracking systems to expedite that effort.

145. Godecke also knows that KCI delivered VACs to patients before all of the WOPD requirements had been satisfied, because she saw the documentation that proves the fact of that KCI behavior in the work she did on appeals of denied claims, and the work that she did on preparations for Medicare audits.

146. But KCI management apparently did not understand that the same reporting systems would also reveal that its common practice of granting exceptions resulted in the submission of false claims.

B. WHEN KCI DELIVERED VACs BEFORE HAVING ALL WOPD ELEMENTS IN ITS POSSESSION, KCI ALSO FAILED TO ADD THE EY MODIFIER TO THE CLAIMS

147. From April 1, 2003 to the present, KCI knowingly submitted and continues to submit claims for payment to the DMERCs/DME MACs without an EY modifier when KCI: (1) did not have in its possession any Detailed Written Order prior to delivery or (2) had some form of a Detailed Written Order prior to delivery, but the order was clearly defective because one of the six required elements was missing. It might have been missing a physician's signature or the date of the prescription. The length of need might not have been provided.

148. The inclusion of the EY modifier is intended to notify Medicare that it should deny the claim, and that such denial was not appealable. KCI violated the FCA by knowingly, as defined in the FCA, not including the EY Modifier as a matter of course, when it clearly was required to do so. In so doing, the company took advantage of the rules it negotiated in order to achieve a quicker payout for legitimate claims without having to obtain prior approval on a case-by-case basis, which is a cumbersome process.

149. Godecke also knows that KCI submitted false claims to Medicare, by submitting claims without the EY Modifier for VACs that were delivered before KCI had all required elements in its possession, because of her work related to 1) KCI appeals of claims denied by Medicare, and 2) KCI preparation for audits by Medicare.

C. EXAMPLES OF KCI FALSE CLAIMS

150. The following table represents fifteen actual claims, identified by ROE Number, as representative examples of the many false claims alleged herein in which

KCI billed Medicare for cycles of VAC therapy which were either based upon inaccurate or incomplete Detailed Written Orders or for which delivery of the VAC preceded KCI's receipt of a Detailed Written Order, and for which the claim submitted by KCI did not have the required EY Modifier.

151. These Rental Order Numbers were taken from a Follow Up report dated July 18, 2006 and Forced Pick Up Lists from 2006 and 2007.

1198842	1197604	1196058	1195999
1143823	6969532	9810077	9579219
6770666	9754948	8949975	6958229
6966928	6823535	6802864	

152. The Follow Up Report enabled Relator Godecke to identify a group of ROEs with the deficiency that KCI did not have a required WOPD element at time of delivery. Call this Group 1.

153. Exhibit 4 is a Final Forced Pick Up Report that Godecke reviewed. It shows eleven VACs at the top of the exhibit and highlighted in yellow is the label "Rx," indicating that the required document that is deficient for those VACs is the prescription. The column entitled "Reason" shows the specific deficiency – that the prescription was not received, or not dated, or did not show the length of need, was not signed, or had incorrect doctor information.

154. The Forced Pick Up list should be read together with Exhibit 5, entitled "Important Information." It explains that for those named in the "Patient" column

and highlighted in yellow, Forced Pick Up will occur, but for those whose names that are highlighted in blue, an Exception has been granted. (The names have been redacted, but the color is visible for the pertinent rows of the exhibit.) Exceptions in the KCI procedures means that management has approved the delivery and billing of a VAC even though KCI records show that WOPD requirements are not satisfied.

155. The Forced Pick Up Reports enabled Relator Godecke to identify those ROEs in Group 1 that were actually not "picked up," those highlighted in blue, even though KCI had not obtained the required documentation. If they were "picked up" under these circumstances, KCI did not submit a bill for them. So, Godecke only kept VACs highlighted in blue in her Group 1 because they were delivered and CAVED for billing. For the examples offered here, the pertinent ROE numbers are 9810077, 9579219 and 9754948. These VACS were at a minimum, in Cycle 2, meaning that they were delivered at least 30 days prior to the date of the Report.

156. To be certain that KCI had submitted claims to Medicare for the ROEs that remained in Group 1 without the EY Modifier, Godecke turned to two of KCI's billing databases, the MicroMD database, the paid/denial report and the appeals claims report. In 2005 KCI converted the Medical Manager billing and collections database to the MicroMD billing and Collections database. All WOPD samples had dates of service in 2006 and 2007. She was in charge of Cash payments and Appeals where she used and accessed the billing database where these reports were created

157. The MicroMD database tracked bills and claims submitted to payors, including Medicare. In this database, she was able to generate a report of claims paid and denied by Medicare for her Group 1 claims. Searching that report for the individual ROEs remaining in Group 1, she identified claims in Group 1 that had been paid by Medicare. If Medicare paid the claim, it was not submitted with the EY Modifier when KCI submitted it to Medicare. Per the LMRP, Medicare would not have paid a claim with the EY Modifier.

158. Godecke also searched for the individual ROEs in Group 1 in KCI's Appeals database. If a claim was appealed, it did not have the EY Modifier when KCI submitted it to Medicare, also per the LMRP. Moreover, Godecke was familiar with the denial codes used by Medicare to explain denial of the claims she chose from the Appeals report to remain in Group 1, and recognized them to be "appealable" denial codes. If the EY Modifier had been appended to any of these claims, they would not be appealable.

159. Using this process, Godecke determined that all fifteen claims in the chart above were either paid or appealed.

160. Thus, Godecke knows that the example ROEs in the chart above not only were delivered despite non-compliance with the Medicare WOPD requirements, but also were actually billed by KCI without an EY modifier, because Medicare would not have paid a claim, or indicated that the claim was statutorily non-covered

which would foreclose the possibility of appeal, if the claim had been submitted by KCI with the EY Modifier.

IX.
KCI CERTIFIED THAT IT WAS FOLLOWING MEDICARE RULES

161. When KCI initially applied to be a Medicare supplier, it certified that it would obey the Medicare rules. KCI repeated that promise each time it completed a new Medicare Supplier agreement of which there have been hundreds. The certification section of the supplier agreement states:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

162. 42 U.S.C. § 1395y(a)(1)(A) sets forth an express condition of payment which explicitly links each Medicare payment to the statutory provision that no payment may be made for items or services which are not reasonable and necessary. Each time KCI submits a claim to Medicare for payment, it is certifying compliance with this statute.

163. KCI uses a form known as the CMS-1500 in order to submit claims to Medicare. The CMS-1500 claim form is a standard document used by providers and

suppliers to submit a claim for payment from various government and private health care programs.

164. Approved suppliers of medical services and equipment to Medicare Part B beneficiaries, like KCI, are required to submit claims for reimbursement on form CMS-1500. 42 C.F.R. § 424.32. Submission of the CMS-1500 form is the *sine qua non* for payment from the Medicare system.

165. The back of the CMS-1500 form contains the following three notices:

> (a) NOTICE: Any person who knowingly files a statement containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.
>
> (b) NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.
>
> (c) NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

166. The CMS-1500 form identifies the government's authority to require information to determine coverage for the item or service under the appropriate government program. For Medicare purposes, the form refers specifically to 42 C.F.R. § 424.5(a)(6) which provides: "Sufficient Information. The provider, supplier,

or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment."

167. The NPWT LMRP (now LCD) expressly states certain circumstances under which some cycles of VAC therapy are "not reasonable and necessary" and thus not covered by Medicare.

168. For those claim lines on the CMS-1500 form where the item does not have a physician's written order, the modifier EY must be attached.

169. Medicare's rules from 2003 forward required that one of the four modifiers be used for each claim.

X.
KCI SUBMITTED FALSE CLAIMS TO MEDICARE WITH REQUISITE SCIENTER

A. THE FCA STANDARD

170. The FCA scienter standard states: (A) mean that a person,

> (A) mean that a person, with respect to information-
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
> (B) require no proof of specific intent to defraud;

B. KCI'S OWN INTERNAL DOCUMENTS SHOW THAT KCI MANAGEMENT KNEW THE WOPD REQUIREMENTS FROM THE BEGINNING

171. On October 1, 2000, KCI's Medicare and Compliance Department issued a memo regarding WOPD requirements. Pam Seay was the contact person

listed in the memo "for additional copies or information," and Seay's internal phone extension was listed as ext. 6384. Among other matters, the memo states the following:

> A. "Prior Written Order: Certain items require a written order for the physician prior to delivery of the product to the Part B patient. All of KCI's products (surfaces and VAC) fall into that category."
>
> B. "**Prior written orders must include the following: Patient name; Equipment or description of therapy ordered; Diagnosis; Length of need; Physician's signature and date**.
>
> C. "In the case of the VAC, prior written order is built into the ISOP (section 4) and by having this fully completed prior to the delivery of the product, KCI is meeting the Medicare requirement." (Emphasis added.)

C. KCI'S OWN PROCESSES SHOW THAT KCI MANAGEMENT KNEW THE WOPD REQUIREMENTS FROM THE BEGINNING

172. As previously explained, the NPWT LMRP was the product of extensive discussion and negotiation between KCI and the DMERCs. One result of these negotiations is that everyone involved knew the outcome of those negotiations, so that KCI management knew exactly what the LMRP required in order for a KCI VAC to be eligible for Medicare reimbursement.

173. If nothing else, the Preliminary Forced Pick Up and Forced Pick Up Reports drove this point home.

174. Exhibits 4 and 5 make clear that KCI management authorized exceptions to its Forced Pick Up procedure, which resulted in the delivery of VACs,

and billing for them, even though the VACs that were granted exceptions did not satisfy the WOPD requirements.

175. The very existence of such processes and tracking tools as the Follow Up Report, the Unbilled by Status Code Report, the Forced Pickup Report, the ISOP form and later the Fast Rx Form, demonstrates that KCI knew that it was delivering VACs without first having a Detailed Written Order on hand prior to delivery and knew that the claim for such a VAC needed to include an EY modifier to be correctly billed. KCI management created a system to track the required WOPD documentation, even after VAC deliveries were made without complying with WOPD requirements.

176. Management knew that if the placement of the VAC involved a situation where, at the time of placement, the Detailed Written Order was inaccurate or incomplete, the DME MACs were required to deny the claim, with no possibility of appeal. Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3.1. But Medicare would not be alerted to the fact of the missing and late documentation unless the correct EY modifier was included on the claim, and KCI purposely did not use the EY modifier.

D. COMPETITION CREATED PRESSURE TO DELIVER VACs MORE QUICKLY

177. KCI had a total monopoly on NPWT from the late 1990's until 2003, when Blue Sky Medical launched the Versatile 1. Blue Sky Medical seemed to have a

great advantage over KCI, in that they seemed able to place their Versatile 1 product remarkably fast. At the time, KCI was taking 24 hours to release a Medicare VAC for delivery, while Blue Sky was providing the Versatile 1 immediately on request. After a year of increasing Versatile 1 placements at KCI expense, KCI's sales management brought immense pressure to bear on the operations side of KCI to release VACs far more quickly to meet the competition. That pressure was focused on Steve Hartpence, as the Executive Committee member with responsibility for releasing the VAC for placement. Hartpence started working hard on this in the summer of 2004, by putting intense pressure on the KCI staff for quick release of all VAC orders, including for Medicare. You can see the resulting radical reduction in release times in Exhibit 6.

178. It was important enough to Hartpence to make further improvement in VAC delivery speed that he agreed to focus a significant part of his 2005 bonus opportunity on further improving Medicare ship pending release times (Objective 2 in Exhibit 7). Hartpence required everyone who worked for him to share these objectives, which resulted in further pressure on MedClaim to release the VACs asap.

179. In December of 2006, a further change was made to improve productivity and decrease release times. That change was to provide a bonus to the MedClaim ship pending clerical staff to release as many VACs as possible as quickly as possible. The result of initiatives undertaken by Hartpence and Medclaim

was that 14% of the staff was eliminated, even as VACs were being released in less than 3 hours. See Exhibit 6.

E. THE EY MODIFIER WAS NOT HARD-CODED INTO THE KCI BILLING AND COLLECTION SYSTEM

180. From early 2005 until mid-2006, KCI was converting its billing and collection systems from the Medical Manager system to a new platform, called MicroMD. Godecke was part of a KCI working group called the MicroMD Conversion Group, which met more than twenty times during that period to review progress of that conversion and in the end, to judge whether MicroMD could provide the same functionality for KCI operations that Medical Manager had provided.

181. Participants in the MicroMD Conversion Group were stakeholders in the process - operations of their various departments in KCI had relied on Medical Manager, and they wanted MicroMD to provide at least the same level of functionality. The Group included Laurie Waldron, Deb Smith, Mary Fisher and Linnet Long. The project management contractor was Bob Hess.

182. During testing of the conversion, a list of Medicare billing modifiers to be included in MicroMD was identified. The list of modifiers included RR, KX, GZ, GA, KI, KJ, and KH. Although the EY modifier was mandated for use beginning on April 1, 2003, through several meetings and at least one demonstration of MicroMD, the EY modifier was never included on the list of medicare billing modifiers that Godecke saw. In both the Medical Manager and MicroMD billing and collection

programs, the EY modifier was not included because KCI made a management decision not to include the EY modifier in claims submitted to Medicare.

F. KCI HANDLING OF APPEALS DEMONSTRATES SCIENTER

183. KCI is very aggressive in challenging claim denials. Godecke was intimately involved in reviewing all claim denials. KCI would challenge every denial unless there was a good reason not to do so.

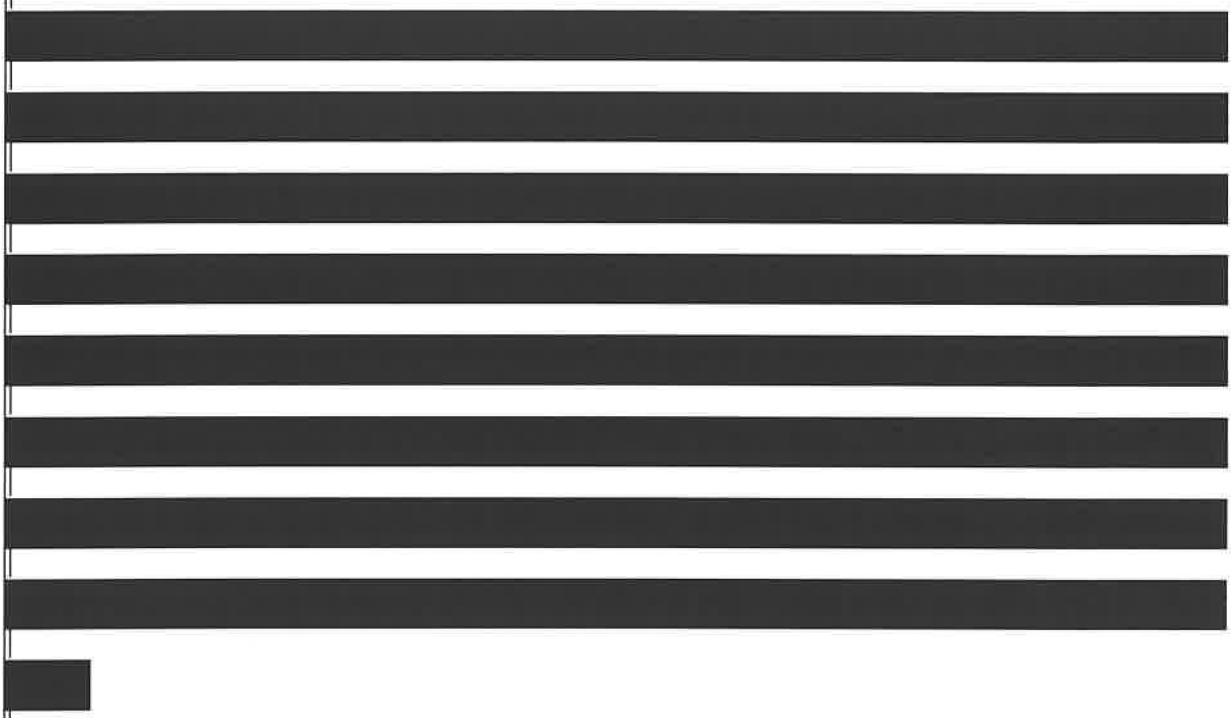
184. One reason not to pursue a claim appeal was that the appeal might expose other problems at KCI and trigger undesired repercussions. One consistent concern was that an appeal could trigger a large-scale audit. Thus, KCI scrutinized its support documentation very carefully, and decided to forego appeals of certain denied claims. Two examples of such decisions were denial of claims for Restarts (continued use of a VAC after a period of non-use) and denial of claims for Fifth Cycles (most Detailed Written Orders are for four months or less. Sometimes, if the wound had not progressed enough, a doctor might still order another month of treatment. This was referred to as a Fifth Cycle.)

185. KCI decided not to appeal denials of claims for Restarts or for a Fifth Cycle when KCI had been paid by Medicare or another insurer for an original round of treatment and the claims for the previous four months of treatment had been filed with a KX modifier instead of an EY modifier. During the evaluation undertaken to decide whether to appeal the denial, the file review might reveal that documentation required for the previous claims in the original months (before Restart or Fifth Cycle)

was untimely or otherwise deficient. For example, wound measurements might have been inaccurate, or dates did not match the requirements. Or the file would reveal that the Detailed Written Order was not completed or was deficient, but the VAC was still delivered. Other issues could become apparent. If anything emerged during that evaluation that could lead an ALJ or Medicare to conclude that the KX Modifier was misused, or that the EY Modifier should have been attached instead, KCI would typically decide not to appeal the denial of the Restart claim.

186. Regarding a decision about appealing a Fifth Cycle claim, Godecke observed that Medicare's scrutiny became more penetrating over time. Early on, Medicare required only the documentation for the Fifth Cycle itself. Later, it became necessary to include documentation for the Fourth Cycle claim as part of the appeal process. Now, the entire history of treatment for the patient is necessary as part of a Fifth Cycle appeal. Any documentation problem identified in that history could result in Medicare disallowance of money paid for the entire course of treatment. A review of the First Cycle claim documentation would show Medicare that WOPD requirements were not satisfied and that KCI had not submitted the claim with the required EY Modifier. KCI viewed those stakes as daunting and typically dropped appeals for the Fifth Cycle to protect the already received payment for the first four cycles. This was done at the direction of management.

187. [redacted]



188. In 2002, Theresa Duffy (Duffy) began work at KCI as a clinical manager. Her job duties included evaluating claims denied by Medicare to determine whether KCI should appeal the denials. When Duffy started working on potential appeals, she observed that claims submitted by KCI lacked proper documentation required by Medicare before submission of the claims. Starting in 2002 and continuing thereafter, Duffy complained to Godecke about the inadequate documentary support for submitted claims. Duffy and Godecke discussed that numerous claims lacked required documentation.

189. Within the last two weeks, Duffy again spoke to Godecke and confirmed that KCI's claims submitted to Medicare that Duffy had personally reviewed lacked appropriate documentation, including claims which required an EY

modifier because KCI did not have a valid WOPD before delivery of a VAC. Duffy confirmed the following to Godecke in their discussion in May 2017:

> A) KCI's billing and management personnel, including Deb Smith, and other KCI personnel with whom Duffy directly communicated, knew that, before a claim for payment was submitted, Medicare required that KCI obtain a valid WOPD before delivery of a VAC. If no WOPD was obtained before delivery of the VAC, the claim submitted to Medicare should be denied.
>
> B) In her review of denied claims for possible appeals, Duffy generally focused on denials of claims for fifth cycle treatment. However, in reviewing the history of those claims, Duffy personally saw that claims for first cycle treatment had routinely been billed to Medicare, and paid by Medicare, even though the VAC had been delivered before KCI had obtained a valid WOPD.
>
> C) Duffy's recollection is that all submitted claims she reviewed for potential appeal of fifth cycle treatment denials had been billed to Medicare for first cycle treatment with a KX modifier. Duffy did not recall ever seeing an EY modifier placed on any first cycle claims, even when Medicare required that an EY modifier be included.
>
> D) Every claim that Duffy considered for possible appeal of treatment denials required Duffy to search for a WOPD. When Duffy reported to KCI management, including Deb Smith, that she had not found any WOPD for claims submitted, Smith directed Duffy not to appeal the claim. Duffy stated that even if the claim for fifth cycle treatment was appropriate, Smith told her not to appeal the denial of the fifth cycle claim because Smith was worried that Medicare would notice the lack of a WOPD. Smith told Duffy that without the required WOPD documentation, Medicare's payments for the first, second, third, and fourth cycles were in jeopardy, because Medicare could demand return of those payments received by KCI.

190. Deb Smith further directed the appeals staff that KCI would not reimburse Medicare for those claims that the appeals staff had discovered should not have been paid.

F. KCI HANDLING OF MEDICARE AUDITS DEMONSTRATES SCIENTER

191. The Medicare audit process differs from the appeal process. The audit process begins with Medicare identifying a sample of claims to review. Medicare notifies KCI about which claims are to be included in the audit, gives KCI a time frame to provide those files, receives those files from KCI, and conducts the audit. During this time, the KCI team scrambles to review those same files. If the KCI team identifies issues on any claims to be audited that could support a refund to Medicare or, even worse, cause an expansion of the scope of the audit, KCI makes a business decision to voluntarily refund to Medicare its payment on that claim. That can have a ripple effect, because VAC treatment occurs over four months and each month is a separate claim. But this approach enables KCI to make itself look like a responsible service provider and, more importantly, avoid an audit on those particular claims, because Medicare will generally not audit files once it is verified that those claim payments have been returned by KCI.

192. Relator Godecke's job functions did more than inform her about the details of KCI's information management systems. They also caused her to review the very specific details of thousands of claim files at KCI. Based on this aggregation

of experience with both denials and audit responses, Relator Godecke knows first-hand that KCI has knowingly failed to comply with the requirements for Medicare payment, and used the KX Modifier when KCI should have attached an EY Modifier to numerous claims.

193. Each of the particular claims that KCI refunded to Medicare to stop an appeal or an audit are false claims, even though KCI later refunded the payment because the claims were false at the time that they were filed.

194. KCI's knowing failure to attach an EY modifier for claims that required inclusion of the modifier, as discussed above, was close to absolute. Despite her substantial and personal experience in reviewing KCI's claims, Relator Godecke cannot remember seeing an EY modifier on any claim that she has ever reviewed in any context – not once.

195. Based on Godecke's personal knowledge and experience, KCI's failure to include an EY modifier is a knowing and deliberate decision by the company.

196. Since at least April 1, 2003, KCI filed Medicare claims without including an EY Modifier on any of the claims. Thus, from at least April 2003 to date, KCI has knowingly violated both the Medicare Program Integrity Manual and the LMRP/LCD. Such claims are false because KCI was prohibited by the terms of the Medicare Program Integrity Manual and the terms of the LMRPs/LCDs from delivering a VAC before receiving a qualifying Detailed Written Order. From April 1, 2003 to date, KCI has been required by the LMRPs/LCDs to bill such claims with the

EY modifier to alert the DME MACs that it had delivered the VAC before receiving the required order. Inclusion of the EY modifier alerts the DME MACs that the claim should be denied as not meeting the benefit category or as being statutorily excluded, the effect of which is to make the claim not subject to correction/ re-billing and make the claim non-appealable.

197. Whether the falsity of the claims arose from delivering a VAC to a patient before actually receiving a qualifying Detailed Written Order or from incomplete or inaccurate content in the Detailed Written Order, the Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §5.2.3 requires the DME MACs to deny such claims as statutorily excluded from coverage under Medicare or as not meeting the benefit category, thereby making the denials non-appealable. Since April 1, 2003, suppliers have been required to include the EY Modifier on each such claim, to alert the DME MACs that those claims should be denied. Failing in any of these requirements also violated the provisions in the Documentation Required and Indications and Limitations of Coverage and/or Medical Necessity sections of the NPWT LMRPs/LCDs, which expressly require a written order before delivery of the VAC. KCI management knew this.

198. For all CMS-1500 claim forms for VAC therapy cycles alleged to be false in this Complaint, KCI purposefully and knowingly ignored the deficiencies which rendered the claims "not reasonable and necessary" under the terms of the LMRP/LCD, and instead concealed the deficiencies by billing the claims for payment

with the KX modifier, while at the same time NOT attaching the EY Modifier to those claims, thereby fraudulently calling upon the government fisc and triggering liability under the False Claims Act.

199. KCI's use of the KX modifier instead of the required EY Modifier on the claims for VAC cycles which are the subject of this Complaint is a false statement or assertion that none of the constraints set forth in the LMRP/LCD which would have rendered the claim "not reasonable and necessary" under the LMRP/LCD apply. By using the KX modifier instead of the required EY Modifier on the CMS-1500 form for such claims, KCI falsely states that it is entitled to payment while knowing, by virtue of the information in its possession at the time the claim was submitted, that one or more of the circumstances described in the NPWT LMRP/LCD which limit or exclude coverage were present.

200. In submitting form CMS-1500 with the KX modifier, instead of the required EY Modifier, attached for the VAC cycles which are the subject of this Complaint, KCI falsely certified compliance with the Medicare Act, specifically 42 U.S.C. § 1395y(a)(1)(A), by asserting that it was not seeking payment for services which were "not reasonable and necessary" as defined by the LCD. By using the KX modifier instead of the required EY Modifier on the claims which are the subject of this Complaint, KCI communicates to the DMERCs (now DME MACs) that the claims were reimbursable. Accordingly, use of the KX modifier instead of the

required EY Modifier has a natural tendency to influence the DMERCs' or DME MACs' decision to pay the claim.

XI.

RETALIATION IN VIOLATION OF 31 U.S.C. § 3730(h)

201. Relator repeats and re-pleads and incorporates by reference herein each and every one of the allegations contained in paragraphs 1 -169 above, as though fully set forth herein.

202. On June 1, 2001, Relator Godecke became employed by MedClaim, Inc., an independent contractor working for KCI. KCI later purchased MedClaim and Godecke continued working for the company until she was terminated on October 1, 2007.

203. At the time of Godecke's hire, the VAC was a newly coded and authorized type of durable medical equipment under Medicare's complex rules. Virtually all billing and collection documents and processes were developed for this device during Relator Godecke's tenure, both at MedClaim and at KCI.

204. As a result of her employment with MedClaim and KCI, Godecke developed a specialized knowledge related to Medicare collections and appeals for the VAC. Godecke began as the office manager in Dillon, Montana with two employees. Under her leadership and direction, and within the next six years, the Dillon, Montana office grew to 105 employees, all of whom were under Godecke's supervision, and all of whom worked on KCI's Medicare collections and appeals.

Godecke and her staff were the day to day contact people within MedClaim and KCI with all DMERC regions in the United States. Godecke and her staff also worked with Medicare Ombudsmen, DMERC/DME MAC clinicians and clinical review teams, Medicare customer service representatives, Fair Hearings Officers, Program Safeguard Contractors (PSCs), Qualified Independent Contractors (QICs), Recovery Audit Contractors (RACs), Administrative Law Judges (ALJs) and the Medicare Appeals Council (MAC). Relator Godecke was the primary contact for KCI's outside counsel for Medicare appeals. The ongoing dialog with the above Medicare divisions increased Relator Godecke's knowledge level of Medicare billing and appeals requirements. With this knowledge, Godecke was able to communicate to KCI's billing department her concerns about KCI's non-compliant processes and procedures.

205. In approximately 2006, based on nominations from KCI Vice President Rich Brinkley and KCI Senior Vice President Steve Hartpence, Godecke was selected and approved by Steve Benson, KCI's Director of Organizational Development, to participate in an intense leadership development program at KCI called "Leading the Enterprise." This was part of the management-level succession planning done by KCI. By having Godecke participate in the leadership development program, KCI was demonstrating that it considered her a future leader of the company. KCI's Human Resources Department would not have invested the money in sending

Godecke to the leadership development conference if it did not concur with Brinkley and Hartpence as to her future potential as a leader of the company.

206. Throughout her tenure at MedClaim/KCI, Relator Godecke had numerous discussions with her management-level superiors at KCI about the false claims alleged herein and other billing compliance concerns. A particular billing concern Relator Godecke attempted to bring to senior management's attention was billing for what KCI internally called "transitions claims." Transition claims arise when a patient transitions between an in-patient facility to the home.

207. KCI management reported in 2007 Q2 that 40% of initial placements of NPWT were to patients transitioning between care settings. A percentage of those claims result in triggering a false cycle for the reasons described below.

208. The normal start date for billing for a cycle of VAC therapy is the Date of Delivery, as evidenced by the date of the patient's signature on a form called Proof of Delivery (POD). This document is required to be in the patient's file. However, an exception to the general rule of billing from the Date of Delivery arises under CMS's Program Integrity Manual, Chapter 4, section 4.26.2, which addresses billing for covered DMEPOS items in anticipation of discharge from a hospital or skilled nursing facility. The policy is focused on billing from the date of discharge and provides, in relevant part, as follows:

> A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to two days prior to the

> patient's anticipated discharge to their home. The supplier should bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) code 12 (Patient's Home). The item must be for subsequent use in the patient's home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility. (Emphasis added.) A supplier may not bill for drugs or other DMEPOS items used by the patient prior to the patient's discharge from the hospital or a Medicare Part A nursing facility stay. Billing the DME MAC for surgical dressings, urological supplies or ostomy supplies that are provided in the hospital or during a Medicare Part A nursing facility stay is not allowed. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the patient from the hospital or nursing facility. Any attempt by the supplier and/or facility to substitute an item that is payable to the supplier for an item that, under statute, should be provided by the facility, may be considered fraudulent. These statements apply to durable medical equipment delivered to a patient in hospitals, skilled nursing facilities (POS §31), or nursing facilities providing skilled services (POS § 32).
>
> A supplier may deliver a DMEPOS item to a patient's home in anticipation of a discharge from a hospital or nursing facility. The supplier may arrange for actual delivery of the item approximately two days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and should use the POS code 12 (Patient's Home). (Emphasis added.)

209. At all times relevant hereunder and continuing to date to the best of Relator Godecke's belief, KCI exclusively uses the date the Proof of Delivery is signed as the start date for billing, regardless of the patient's date of discharge as required by CMS's Claims Processing Manual.

210. In December 2006, Relator Godecke participated in a telephone conference call with Godecke's business analyst Linnet Long and KCI Vice President of Finance Theresa Johnson. The purpose of the call was to review the nature and

scope of denied claims still booked as revenue by KCI and to assist Theresa Johnson in determining how much cash KCI needed to set aside in reserves for year-end 2006. During the call, the volume of transition claims was discussed, particularly the fact that KCI's existing processes required that the improperly paid claims be refunded to Medicare, then re-billed with the date of discharge rather than the date of delivery. The amount in question was several million dollars-worth of transition claims. Godecke explained to Johnson that KCI would not even have the problem if the Pre-Billing Department in North Carolina would only obtain the date of discharge of a patient from an in-patient facility rather than simply initiate billing from the date of delivery. Theresa Johnson expressed concern that the billing rules for transitions claims appeared to be violated. Later, Deb Smith de-emphasized the issue with Theresa Johnson and directed her attention away from the issue.

211. In the spring of 2006, Godecke attended a meeting in South Carolina with the head of Medicare's Qualified Independent Contractor (QIC). Two of Godecke's managers in the Montana office, Jera Sitton and Theresa Duffy, attended the meeting with Godecke. At the meeting, Godecke and her managers disclosed to Godecke's supervisor, KCI Vice President Deb Smith, that the deadline had passed for some Medicare appeals the Montana office was pursuing. Godecke, Sitton and Duffy were instructed by Deb Smith to "change the dates on which we received the denied appeals." Godecke and her managers decided that as a matter of business ethics, they could not falsify the dates and that they simply would not follow Deb

Smith's instruction. Godecke said nothing further about the situation until KCI's internal auditors emailed various KCI employees an anonymous questionnaire a couple months later. The questionnaire asked the KCI employees whether a superior had asked them to do anything that made the employees feel uncomfortable. Godecke ignored replying to the questionnaire because she was reluctant to report Deb Smith's instruction to change the dates of receipt of the denied appeals. Ultimately, Godecke's failure to respond to the email was noticed by KCI's internal auditors who contacted her and directed her to fill out and return the questionnaire. Godecke then submitted the questionnaire and detailed the incident in which Deb Smith instructed Godecke and others to change dates on documents in order to remain within Medicare's filing limits. Godecke and her two Montana managers who heard Smith's instruction (Jera Sitton and Theresa Duffy) knew Smith was directing them to commit fraud, and they agreed not to do so. Thereafter, KCI changed Godecke's reporting supervisor to KCI Senior Vice President Steve Hartpence instead of Deb Smith. Hartpence later assigned KCI Vice President Rich Brinkley as Godecke's supervisor, though Hartpence retained a direct relationship with Godecke and issues with the Montana office.

212. Before the change in reporting for the Montana office from Deb Smith to Richard Brinkley, the Montana office staff had learned to be cautious about what they said to Deb Smith. This caution developed, in part, after an incident in approximately 2005 when another of Godecke's employees, Supervisor Candi

Richardson, reported an incident to the Medicare Fraud Line about Andy Hunter, Director of Pre-Billing in KCI's North Carolina offices. Richardson called to report that she believed Mr. Hunter was regularly waiving patients' co-insurance, a serious Medicare violation. Medicare requires that every patient's twenty percent co-insurance amount be billed to the patient's secondary insurance company or to the patient. Deb Smith came to the Montana office, discovered who made the call to the Medicare Fraud Line, and physically charged after Candi Richardson in an aggressive manner, making Richardson believe Deb Smith was going to physically assault her. Godecke later convinced Richardson not to report Smith's behavior as it would only make working under her supervision more difficult.

213. In September 2006, after Relator Godecke was removed from Deb Smith's supervision and placed under Rich Brinkley, Brinkley began to support Godecke's efforts to access and gather data involving the false claims Godecke believed KCI had been filing. Previously, Deb Smith had repeatedly denied Godecke access to such information and data. Brinkley told Godecke that he could not act on her allegations of improper billing alone, but that if she could assemble some proof and data so that the volume of suspected false claims could be quantified, then Brinkley could take the matter to KCI Senior Vice President Steve Hartpence and after Hartpence's termination, to his replacement, Vice President Theresa Johnson. The "transition claims" were the first category on which Godecke began working.

214. Godecke expressed frustration to Brinkley that it was necessary for her to quantify the false claims, but Godecke understood that KCI's senior management would need to weigh the risk of filing the false claims against potential business losses of not seeking Medicare payment for the claims Godecke was concerned about. Godecke became convinced that quantifying the risk to KCI was the only way to address her concerns about KCI's false claims and fraudulent billing practices.

215. In July 2007, after being allowed by Rich Brinkley and Steve Hartpence to request customized reports from KCI's Information Technology department, Godecke believed she had quantified the transition claims issue well enough to more formally challenge KCI's practice of refusing to bill transition claims from the date of hospital discharge rather than the date of delivery of the VAC to the patient's home. Rich Brinkley agreed and he arranged a meeting at KCI's headquarters in San Antonio, TX between Godecke, Brinkley, and KCI Senior Vice President Hartpence. During the meeting, Steve Hartpence brought Deb Smith into the meeting via telephone conference call. Deb Smith disputed Godecke's interpretation of the Medicare rules regarding transition claims and insisted that it was too costly and cumbersome to research the actual date of discharge from the in-patient facility before releasing a VAC for delivery to the patient's home. Steve Hartpence requested that Godecke continue and complete her research so that the risk could be better quantified. Within hours of the meeting, Steve Hartpence was fired and escorted out of KCI's building. KCI Vice President Theresa Johnson replaced Hartpence.

216. One of Relator Godecke's final discussions involving "transition claims" occurred in late August or early September 2007, shortly before Godecke was fired. Godecke was a participant in a strategic telephone conference with Linnet Long (KCI Business Systems Analyst), Theresa Duffy (KCI Clinical Manager), Shannon Truman (KCI Appeals Supervisor), Deb Smith (Vice President, KCI-MedClaim), Scott Jones (Director of KCI's Intern Audit Department), Theresa Johnson (KCI Vice President) and others. The parties to the telephone conference discussed compliance risks regarding recent Medicare-audited claims. During the conference, "transition claims" was one of the topics (as well as "Restarts," "risk sharing", "wounds too small", and other KCI compliance concerns). Deb Smith continued to insist that Godecke's concerns regarding billing from delivery dates versus properly billing from discharge dates was too cumbersome. Deb Smith stated that if a "transition claim" did get billed, the DME MAC would catch the error, and it would be a situation of "no harm no foul" because the DME MAC would then simply deny the claim. Godecke insisted that not billing from the date of discharge was plainly contrary to Medicare rules. Godecke stated that she had assembled a report analyzing approximately 2,500 claims for the purpose of identifying those circumstances in which cycles for in-patient VAC therapy under Medicare Part A overlapped with cycles for therapy in the home setting under Medicare Part B. Godecke advised the group that her research to date was indicating that there were a significant number of overlapping claims which could be false due to KCI's refusal to

perform the labor-intensive work of obtaining discharge dates from which to initiate billing. Godecke was reprimanded during the telephone conference by KCI Vice President Theresa Johnson because of her insistence.

217. Within two weeks following the conference call described in the paragraph above, still in September 2007, Relator Godecke had completed her analysis and determined that approximately one half of the claims in her sampling contained overlapping claims between Medicare Parts A and B which the DME MACs had not caught and which had been paid. Godecke then held a one-on-one telephone conversation with KCI Vice President Theresa Johnson for the purpose of trying to convince her of the seriousness of the issue and that what Deb Smith had been saying (i.e., that all overlapping claims were caught and denied by the DME MACs) was not accurate. Godecke warned Ms. Johnson that KCI needed to revise its process, obtain information on the date of discharge before initiating the billing process, start billing the transition claims properly, and analyze how many improperly paid claims KCI needed to refund to Medicare. Ms. Johnson was dismissive of Godecke's concerns and terminated her employment in a matter of weeks thereafter.

218. KCI Vice President Theresa Johnson had been in charge of KCI's Medicare issues for approximately six weeks before she fired Godecke in late September 2007. Approximately one or two weeks before Godecke was fired, her immediate supervisor, KCI Vice President Rich Brinkley was fired. After he was fired, Rich Brinkley called Godecke to advise her that he believed KCI was preparing

to fire Godecke because senior management told him she was going to be a whistleblower. Brinkley advised Godecke that KCI's senior management believed Godecke had access to information that would identify false and fraudulent claims, and moreover, that Godecke was assembling the documentation into reports that would reveal false and fraudulent claims. Brinkley told Godecke to "keep that information in your back pocket in case you need it." Brinkley then explained to Godecke that one of the reasons he was fired was because he had refused to fire Godecke.

219. In September 2007, KCI Vice President Theresa Johnson and KCI in-house counsel Kay Behrens arranged a trip from KCI headquarters in San Antonio, TX to Dillon, MT to meet in person with Godecke over various issues, including Godecke's compliance concerns. The trip was to occur the last week of September 2007. The day before arriving in Montana, Theresa Johnson asked Godecke to compile a list of her compliance concerns and send it to her. Godecke decided to provide the list to Theresa Johnson and Kay Behrens in person the following day.

220. On or about September 27, 2007, Theresa Johnson called Godecke at the Dillon, MT KCI offices and asked her to come to Johnson's Dillon, MT hotel room to meet. Unbeknownst to Godecke, KCI Human Resources Director Louis Riviera had also traveled to Montana with Johnson and Behrens.

221. As requested, Godecke met Theresa Johnson, Kay Behrens and Louis Riviera on or about September 27, 2007 at the Guest House Inn, a Dillon, MT hotel.

When she arrived, Theresa Johnson fired Godecke. Theresa Johnson had a termination agreement prepared and delivered it to Godecke, asking Godecke to sign and return the agreement. A copy of the termination agreement is attached hereto as Exhibit 9. The termination agreement provided, inter alia, that KCI would pay a year's salary, Ninety-Four Thousand Two Hundred Fifty-Six Dollars ($94,256.00), less withholdings, to Godecke in exchange for Godecke's agreement to immediately surrender to KCI any and all documents, electronically stored data, computers and other property of KCI and to not disclose any of KCI's confidential information. Specifically, the termination agreement provided, in part, as follows:

> Further, in consideration for the Severance Payment made by KCI pursuant to this letter agreement, and because of your close contact with many confidential affairs of KCI, including all matters related to KCI's business, such as information concerning customers, plans to acquire prospective customers, business plans, costs, profits, markets, operations, sales, trade secrets, and plans for future developments and any other proprietary information which is not publicly available or readily ascertainable by independent investigation, which information was imparted to you because of and during your employment by KCI (hereinafter collectively referred to as "confidential matters"), you agree at all times to protect from damage or destruction and to keep secret and confidential all confidential matters of KCI. Additionally, you agree not to disclose any confidential matters to anyone outside of KCI or otherwise use those confidential matters or your knowledge of the confidential matters for your own benefit or for the benefit of any other person other than KCI. . . .
>
> As additional consideration for the Severance Payment, you represent and warrant that you have brought to the attention of KCI's Legal Department and /or KCI's Health

> Care Compliance Department all material issues pertaining to any known or suspected situations, arrangements or scenarios where you believe that KCI or any of its employees or contractors may have acted, or may be acting, in a manner that is not compliant with federal or state laws, regulations, policies or guidance. You further represent and warrant that your notice of any such issues has been made in a manner that will reasonably afford KCI the opportunity to investigate and address any such issues. . . .
>
> Except as required by applicable law, the terms and conditions of this letter agreement shall remain confidential and you shall not respond to or participate in any public discussion or other publicity concerning or relating to your employment with, resignation or separation from KCI. You agree and covenant not to make any derogatory or negative comments about KCI, its management, operations or financial condition and agree to cooperate with KCI to the extent reasonably necessary regarding the transition of matters worked on by you during your employment with KCI.

222. Theresa Johnson demanded that Godecke immediately surrender to her the keys to the Dillon, MT KCI office and told Godecke that she was not allowed to return to her office at KCI. Theresa Johnson advised that someone from the office would box up her belongings and deliver them to Godecke.

223. Godecke was upset and emotional and left the hotel room. Later in the morning, she composed herself and called Theresa Johnson to ask if she and Kay Behrens would meet with her for lunch. Behrens had already left Dillon, MT and was half way to the airport, but she turned around, returned to Dillon and met with Godecke and Johnson. During this meeting, Godecke explained in detail for Johnson and Behrens what she viewed as compliance issues and risks at KCI. Godecke told

Johnson and Behrens that she believed that by ignoring the concerns, KCI was committing criminal activities. Johnson and Behrens listened to Godecke's concerns and then thanked her for explaining the issues. Johnson told Godecke that she would address Godecke's concerns.

224. Godecke refused to accept the severance money and told Theresa Johnson that she considered it "blood money." Godecke also refused to execute the termination agreement and received no severance pay from KCI.

225. Throughout her tenure at MedClaim and KCI, Godecke addressed her billing compliance concerns to Andy Hunter, KCI's Director of the Medicare Pre-Billing Department in North Carolina. Ironically, Andy Hunter was also MedClaim's and KCI's Compliance Officer with respect to Medicare billing. Godecke long believed that Andy Hunter had a conflict of interest as Compliance Officer and Director of Pre-Billing because he was under constant and significant pressure from KCI senior management to increase KCI's Medicare profits. Hunter was also rewarded with performance bonuses based upon various factors including how quickly his department could release VACs for delivery.

226. In addition to discussing her compliance concerns with Andy Hunter, Deb Smith, Rich Brinkley, Steve Hartpence and Theresa Johnson, as described in part above, Godecke also discussed her compliance concerns in detail and frequently with KCI's Medicare consultant Tom Walters, KCI's internal auditor Scott Jones, KCI's Compliance Officers in the San Antonio, TX headquarters David Jernigan and Pam

Seay, and KCI's in-house counsel Kay Behrens and outside counsel Donna Thiel. In working closely with these KCI employees and consultants during her tenure, Godecke learned a great deal about Medicare billing and became increasingly certain that KCI was submitting false claims under a number of circumstances, including those which are the subject of this Complaint.

227. At the time of Relator's termination, she was earning a base salary of approximately $94,000.00 per year, in addition to generous bonuses which varied year to year based upon KCI's financial performance. In addition, Relator enjoyed health insurance, life insurance and options to purchase KCI stock, which she regularly exercised. KCI also gifted stock to Godecke annually depending on the company's performance and the individual department performance.

228. As a result of her wrongful termination from employment at KCI, Relator has suffered economic losses in the form of lost wages and lost benefits. Relator has also suffered significant emotional distress and mental anguish as a result of her wrongful termination from employment at KCI.

229. Relator was harassed, retaliated against, discriminated against in the terms and conditions of her employment, and fired from her employment at KCI in direct retaliation for her efforts to investigate or otherwise address the false claims described in this Complaint, as well as other types of false claims, her efforts to change KCI policy to comply with Medicare coverage and billing requirements, and

her resistance to the submission of false claims. KCI violated 31 U.S.C. § 3730(h) by carrying out the acts against Relator Godecke as described herein.

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EXHIBIT LIST OF RELATOR GODECKE

EXHIBIT 1	Local Medical Review Policy published by Region C DMERC (Palmetto Government Benefits Administrators) in October, 2000.
EXHIBIT 2	Initial Statement of Provider
EXHIBIT 3	Fast Form Rx
EXHIBIT 4	Forced Pickup Report - Redacted
EXHIBIT 5	FPU Important Information
EXHIBIT 6	MedClaim Release Times
EXHIBIT 7	2005 Hartpence MBO
[redacted]	[redacted]
EXHIBIT 9	Termination Agreement

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: MAY 15, 2017

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The filer, Mark I. Labaton, attests that all other signatories listed, on whose behalf this filing is submitted, concur in the filing's content and have authorized the filing.

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PROOF OF SERVICE BY ELECTRONIC POSTING

I, the undersigned say:

I am not a party to the above case, and am over eighteen years old. On June 26, 2017, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Central District of California, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on June 26, 2017, at Los Angeles, California.

s/ Mark I. Labaton
Mark I. Labaton

Mailing Information for a Case 2:08-cv-06403-BRO-AGR United States of America et al v. Kinetic Concepts, Inc.

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

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